

EXHIBIT B

Elizabeth Kavalier, M.D.

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SUPERIOR COURT OF NEW JERSEY
LAW DIVISION - ATLANTIC COUNTY

DOCKET NO. ATL-L-6966-10

LINDA GROSS and JEFFREY GROSS :MASTER CASE
Plaintiffs, :NO.
v. :L-6341-10-CT
:
GYNECARE, ETHICON, INC., JOHNSON & :Civil Action
JOHNSON, and JOHN DOES 1-20 :Case No. 291
Defendants. :

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Tuesday, December 4, 2012

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Transcript of the videotaped deposition of
ELIZABETH KAVALER, M.D., called for examination in
the above-captioned matter, said deposition taken
pursuant to Superior Court Rules of Practice and
Procedure by and before Kimberly A. Otherwise, a
Certified Realtime Reporter, Registered Professional
Reporter, Certified Court Reporter, and Notary
Public, at Riker Danzig Scherer Hyland Perretti,
LLP, 500 Fifth Avenue, New York, New York, on the
above date, beginning at 9:41 a.m.

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1 relying on any specific standards for, you know,
2 what constitutes an adequate warning or not?

3 MS. KABBASH: Objection.

4 THE WITNESS: Do we have the IFU?

5 Can we look at it or --

6 BY MR. SLATER:

7 Q I'm asking -- I'm not asking about any
8 specifics within it.

9 A Right. Okay.

10 Q I'm asking when you formed your opinions
11 and said that the warnings were adequate in the IFU,
12 were you relying on any particular standards to give
13 that opinion?

14 MS. KABBASH: Objection.

15 THE WITNESS: For me -- I was saying
16 for me, for my experience as a pelvic surgeon, they
17 were adequate for me, and I'm a --

18 BY MR. SLATER:

19 Q Based on your own -- I'm sorry.

20 A -- I'm a regular pelvic -- you know, I'm
21 just -- I'm another -- I'm a standard pelvic
22 surgeon.

23 Q So your opinions with regard to the
24 adequacy of the warnings in the IFU for the Prolift®
25 were based on your own personal experience, your

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1 personal standards; correct?

2 A Right.

3 Q And am I correct that you don't have any
4 information as you sit here now as to what, for
5 example, Ethicon medical affairs thought was a
6 standard or was a criteria for whether or not a
7 warning would need to be included in the IFU? I'm
8 correct; right?

9 A Right.

10 Q And you as you sit here now have no idea
11 as to what standards the people within regulatory
12 affairs at Ethicon thought applied, what criteria
13 applied, to whether or not warnings had to be
14 provided or how they had to be provided in the IFU;
15 correct?

16 MS. KABBASH: Objection.

17 THE WITNESS: Right. You mean the
18 medical affairs people and the regulatory people?
19 Is that what you're asking? Yeah, I don't know what
20 their -- why they did -- I don't know what their
21 opinion is, no.

22 BY MR. SLATER:

23 Q You don't know what standards Ethicon
24 internally was applying in deciding what to warn
25 about and how to warn about those things in the IFU;

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1 correct?

2 A Right.

3 Q And the same would hold true with regard
4 to the patient brochure; correct?

5 A Right.

6 Q The POP-Q is a system used for a physician
7 or whoever's doing the measurements to actually
8 objectively measure the degree of prolapse a woman
9 has; correct?

10 A Yeah. It's sort of a communication
11 system. It's not completely objective, but it's --
12 that's the goal, yes.

13 Q And let me ask a little more on that. The
14 POP-Q measurement system provides a grading system
15 that people can refer to to understand what is being
16 communicated about the degree of prolapse a woman
17 has; correct?

18 A Yes, that's right.

19 Q In actually performing a POP-Q
20 measurement, there's a subjective element depending
21 on the judgment of the person doing the
22 measurements, for example; correct?

23 A Right.

24 Q Also depending on what the woman is doing
25 when the measurements are being taken; correct?

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1 use the Baden-Walker system?

2 A Yes.

3 Q Do you use the Baden-Walker Halfway
4 system?

5 A I don't know what that is. I use the
6 Baden-Walker system.

7 Q I've seen references to a Halfway system
8 that's somewhat of a modification and shorthand.
9 That's not something you're familiar with?

10 A No.

11 Q You're not familiar with the term
12 "Baden-Walker Halfway system"?

13 A No.

14 Q Am I correct that you have no
15 understanding as to what Ethicon internally had as a
16 design intent with regard to the Prolift®, meaning
17 their technical intent for what they expected and
18 wanted the Prolift® to do? You don't know
19 internally what Ethicon's thoughts on that were;
20 correct?

21 MS. KABBASH: Objection.

22 THE WITNESS: I don't know what their
23 discussions were. I just know the product that they
24 produced.

25

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1 had been doing Prolift®, I was using mesh. A lot of
2 this information -- my issue was safety in using
3 trocars and being able to implant it. A lot of this
4 data is their experience, which is important to me
5 as a clinician, but I have my own experience.

6 BY MR. SLATER:

7 Q Am I understanding correctly that in terms
8 of your evaluation of -- well, rephrase.

9 Am I correct that in terms of your looking
10 at literature, listening to other people's
11 experiences, whatever it is, you listen to that, but
12 from your perspective what really matters to you and
13 what you focus on as being significant is your own
14 personal experience with your own patients?

15 A That's -- it's all part and parcel, but at
16 some point I have a body of my own experience which
17 I can then gauge against the literature. So that's
18 correct.

19 Q And in terms of your opinions in this
20 case, you're basing those on your own personal
21 experience as opposed to what may be in the
22 literature and what may be other people's
23 experiences; correct?

24 A Right.

25 MS. KABBASH: Objection.